

1

DETECTION AND MONITORING OF ATRIAL FIBRILLATION

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims priority of U.S. Provisional Application No. 61/818,207, entitled DETECTION AND MONITORING OF ATRIAL FIBRILLATION, filed on May 1, 2013, which is incorporated by reference herein in entirety and for all purposes.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

This invention was made partially with U.S. Government support from the United States Army under grant #215700. The U.S. Government has certain rights in the invention.

BACKGROUND

These teachings relate generally to methods and systems for detection and monitoring of Atrial Fibrillation (AF).

The prevalence of AF is increasing (20.7 per 1,000 patient years (2)), especially among the growing number of older Americans. At age 55, the lifetime risk for developing AF is approximately 1 in 5 and it is estimated that 16 million individuals may be affected by 2040. The growing population burden of AF has widespread clinical and public health relevance, since AF is closely linked to increased risk for stroke and heart failure, as well as diminished quality of life and longevity. Novel treatments for AF, such as catheter-based ablation, exist but require post-treatment monitoring to establish treatment response. To date, traditional methods of AF detection have been confounded by the often paroxysmal and minimally symptomatic nature of this arrhythmia. Brief, asymptomatic episodes of AF remain associated with increased morbidity and mortality, highlighting the need for sensitive AF screening instruments that do not rely on patient symptoms. Contemporary screening for AF involves the use of continuous ambulatory electrocardiographic monitoring (Holter) or longer-duration symptom-triggered (Event) monitors. The detection of arrhythmias via a smartphone application, on the other hand, could lead to many people self-screening even if asymptomatic, if there was sufficient publicity about the dangers of AF and the application was widely adopted. Certainly the barriers to adoption are very low, as most people perceive using the application as fun, which no one has ever claimed about wearing a Holter monitor. Although monitors with automated AF detection capabilities are increasingly utilized to screen for serious atrial arrhythmias, especially after AF ablation, they are severely limited by motion and noise artifacts and an inability to discriminate between AF and other atrial arrhythmias. The ideal AF detection tool would provide real-time, automatic detection of AF in a sensitive and specific manner. Furthermore, since AF is often associated with the clinically relevant, but distinct, premature beats (PVC and PAC), the ideal AF screening instrument would also be able to recognize PVC and PAC.

Atrial Fibrillation (AF) is the most common sustained dysrhythmia worldwide. Over 2.3 million Americans are currently diagnosed, and the prevalence of AF is increasing with the aging of the U.S. population. Through its association with increased risk for heart failure, stroke, hospitalization and mortality, AF has a profound impact on the longevity and quality of life of a growing number of Americans. Although

2

new AF treatment strategies have emerged over the last decade, a major challenge facing clinicians and researchers is the paroxysmal, often short-lived, and sometimes asymptomatic nature of AF.

Although the population with undiagnosed AF is substantial, studies have shown that more frequent monitoring can improve AF detection. There is therefore a pressing need to develop methods for accurate AF detection and monitoring in order to improve patient care and reduce healthcare costs associated with treating complications from AF. Such a method would have important clinical and research applications for AF screening as well as for assessing treatment response (e.g. after cardioversion or AF ablation). For these reasons, the importance of developing new AF detection technologies was emphasized by a recent NHLBI Expert panel.

Since the standard-of-care for detection of AF relies on the arrhythmia being present during an electrocardiogram (ECG), a great deal of serendipity is required in the diagnosis of this often intermittent arrhythmia. A more effective AF detection strategy requires a readily available and cost-effective monitoring device that could be operated by a patient on a daily basis, combined with an accurate, real-time AF detection algorithm. The ideal AF monitoring device would be accessible, inexpensive, and simple to operate in order to be widely accepted by individuals with, or at risk for, AF.

A smartphone application to measure heart interval series and then use this data to detect AF real-time was previously developed. That approach uses standard phone components and does not require extra hardware, as the optical video monitoring of the skin with the standard digital camera embedded in smartphones is sufficient to detect variability in the heart rate signal (see FIG. 8), indicating that accurate pulse interval data can be obtained. A set of statistical algorithms has been developed that can accurately identify AF using signatures of near-random characteristics in the pulse intervals. That AF detection method is real-time realizable and has demonstrated a sensitivity of 94.4% and specificity of 95.1% for detection of AF beats using data from the MIT-BIH AF database. For clinical applications, however, it is enough to detect AF episodes, and an episode detection rate of 100% has been achieved. In a recent prospective clinical investigation involving 76 participants with AF, it was demonstrated that the smartphone-based AF detection approach discriminated AF from normal sinus rhythm. Although that algorithm is robust for AF detection, a major limitation is that it is not designed to discriminate premature ventricular contractions (PVC) and premature atrial contractions (PAC) from AF. Consequently, that AF algorithm has resulted in false detection of AF in the presence of many PAC/PVC episodes interspersed with normal sinus rhythm (NSR) because the presence of many PAC/PVC episodes interspersed with NSR can mimic the random dynamics of the AF.

There is a need to enhance the real-time realizable AF algorithm for accurate detection of, and discrimination between, NSR, AF, PVC, and PAC.

BRIEF SUMMARY

Enhanced real-time realizable AF algorithm for accurate detection of, and discrimination between, NSR, AF, PVC, and PAC are disclosed herein below.

In one or more embodiments, the method of these teachings includes an AF detection method having a modified Poincare approach in order to differentiate various patterns of PAC and PVC from NSR and AF.